UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	06 MD 1789 (JFK)
This document relates to: Boles v. Merck & Co., Inc., No. 06 Civ. 9455 (JFK)	**OPINION AND ORDER**

APPEARANCES

For Plaintiff Shirley Boles:

LEVIN, PAPANTONIO, THOMAS, MITCHELL, RAFFERTY & PROCTOR, P.A.

By: Timothy O'Brien, Esq.

For Defendant Merck Sharp & Dohme Corp.:

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JOHN F. KEENAN, United States District Judge

JOHN F. KEENAN, United States District Judge:

Plaintiff Shirley Boles ("Boles" or "Plaintiff") seeks compensatory damages for injuries allegedly suffered as a result of her use of Fosamax, a drug manufactured by defendant Merck Sharp & Dohme Corp. ("Merck" or "Defendant"). This is one of over 900 cases consolidated for coordinated pretrial proceedings as part of the In re Fosamax Products Liability Litigation, No. 06 MD 1789, multidistrict litigation (the "Fosamax MDL"). It is also one of several Fosamax MDL cases selected for trial as bellwethers, and to date has been tried twice: the first trial ended in a hung jury, and the second trial resulted in an $8 million verdict in favor of Plaintiff. At the conclusion of the second trial, Merck renewed its motion for judgment as a matter of law and moved in the alternative for a new trial. In its Opinion and Order dated October 4, 2010, the Court denied both motions and ordered a remittitur of the verdict to $1.5 million. In re Fosamax Prods. Liab. Litig., 742 F. Supp. 2d 460, 486 (S.D.N.Y. 2010) ("October 4, 2010 Opinion and Order"). Subsequently, Plaintiff rejected the reduced verdict and requested a new trial on damages.

Before the Court is Merck's motion for certification of the Court's October 4, 2010 Opinion and Order for interlocutory appellate review pursuant to 28 U.S.C. § 1292(b). For the reasons stated below, the Court certifies that its October 4,

2010 Opinion and Order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from its October 4, 2010 Opinion and Order may materially advance the ultimate termination of this litigation and the Fosamax MDL.

I. Background

A. The Fosamax MDL

Alendronate sodium, a drug sold by Merck under the brand name "Fosamax," belongs to a class of drugs called bisphosphonates. Physicians use these drugs to treat abnormalities in the bone remodeling cycle that arise from metabolic and oncologic diseases. Fosamax is administered orally, and is generally prescribed at lower doses than intravenously administered bisphosphonates. The U.S. Food and Drug Administration ("FDA") approved Fosamax for the treatment of osteoporosis in 1995. In 1997, the FDA approved Fosamax for the prevention of osteoporosis. Since October 2003, published reports have described the development of osteonecrosis of the jaw ("ONJ"), a condition characterized clinically by an area of dead jaw bone that becomes exposed to the oral cavity, among some bisphosphonate users. Symptoms include pain, swelling, and purulent secretion. The vast majority of ONJ cases have been reported in patients taking intravenously administered bisphosphonates. Reported alternate causes of ONJ include

radiation therapy to the head and neck, osteomyelitis (inflammation or infection of bone marrow), osteopetrosis, herpes zoster virus infection, chemotherapy, and major trauma. See In re Fosamax Prods. Liab. Litig., 645 F. Supp. 2d 164, 169–71 (S.D.N.Y. 2009).

As stated above, the Fosamax MDL consists of over 900 cases alleging that Fosamax causes ONJ and related jaw injuries. On August 16, 2006 the Judicial Panel on Multidistrict Litigation consolidated before this Court all cases involving allegations that Fosamax use had caused ONJ. In re Fosamax Prods. Liab. Litig., 444 F. Supp. 2d 1347 (J.P.M.L. 2006). Two months later, on November 1, 2006, the Court ordered the parties to develop a schedule for discovery and pretrial motions in twenty-five cases to serve as a pool for the selection of three cases for bellwether trial. (Case Management Order No. 3, ECF No. 5).[1]

In addition to this case, two others were selected for trial: Flemings v. Merck & Co., Inc., 06 Civ. 7631 (JFK); and Greene v. Merck & Co. Inc., 06 Civ. 5088 (JFK). After the Court dismissed the Greene case on the plaintiff's Rule 41(a)(2) motion, see In re Fosamax Prods. Liab. Litig., No. 06 Civ. 5088 (JFK), 2008 WL 5159778 (S.D.N.Y. December 10, 2008), Merck selected Koor v. Merck & Co. Inc., 06 Civ. 4110 (JFK), to

[1] The docket numbers in this Opinion and Order refer to the Boles docket rather than the Fosamax MDL docket.

replace Greene. In Flemings, the Court granted summary judgment in favor of Merck, In re Fosamax Prods. Liab. Litig., No. 06 Civ. 7631 (JFK), 2009 WL 4042769 (S.D.N.Y. Nov. 23, 2009), aff'd Flemings v. Merck & Co., Inc., 399 Fed. App'x 672 (2d Cir. 2010), and that case was replaced with Graves v. Merck & Co., Inc., No. 06 Civ. 5513 (JFK).

So far, the bellwether trial process has resulted in two verdicts in favor of Merck and one, this case, in favor of a plaintiff. The first Boles trial ("Boles I") was held in August 2009 and resulted in a mistrial after the jury failed to reach a verdict. Koor--then captioned Maley v. Merck & Co. Inc.--was tried in April 2010, and the jury returned a verdict in favor of Merck. Next the Court held a retrial of Boles ("Boles II") in June 2010. Boles II resulted in an $8 million jury verdict, which the Court reduced to $1.5 million.

Finally, the Graves case was tried in November 2010 and resulted in a second jury verdict in favor of Merck. The Court has set firm trial dates for three additional bellwethers: September 7, 2011 for Secrest v. Merck & Co., Inc., 06 Civ. 6292 (JFK); November 7, 2011 for Raber v. Merck & Co., Inc., 06 Civ. 6295 (JFK); and May 7, 2012 for Jelemma v. Merck & Co., Inc., 09 Civ. 4282 (JFK). The selection of an additional case for a bellwether trial is pending.

The plaintiffs in Boles, Graves, and Secrest were all Florida residents and therefore those cases involved the application of Florida products liability law. Merck has represented to the Court that approximately one hundred of the cases in the Fosamax MDL similarly involve Florida residents.

B. Shirley Boles' Claims Against Merck

Boles alleges that she began to develop symptoms of ONJ after using Fosamax for five years. After having a tooth extracted in August 2002, Boles experienced complications resembling an infection. Standard treatment methods were not effective, and by late 2005 Boles' condition deteriorated to the point that she had exposed necrotic jaw bone in the oral cavity. She continued to suffer from numerous jaw complications, including the development of draining fistulae under her chin. These jaw injuries restricted her ability to eat and she has suffered significant pain.

Boles filed her case against Merck in the U.S. District Court for the Northern District of Florida. The case was transferred to this Court by order of the J.P.M.L in October 2006, and, as indicated, selected for trial as a bellwether two years later. Prior to the Boles I trial, Plaintiff withdrew her claims for breach of express and implied warranty, and the Court granted summary judgment in favor of Merck with respect to Boles' punitive damages claim. See In re Fosamax Prods. Liab.

Litig., 647 F. Supp. 2d 265, 283–285 (S.D.N.Y. 2009). At the close of evidence in the Boles I trial, the Court granted Merck's motion for judgment as a matter of law on Plaintiff's claims for fraudulent misrepresentation and concealment, (see Boles I Trial Tr. 2359–60, Sept. 1, 2009, ECF No. 178), and after declaring a mistrial, the Court granted Merck's renewed motion for judgment as a matter of law on Plaintiff's negligent and strict products liability failure to warn claims, see In re Fosamax Prods. Liab. Litig., No. 06 Civ. 9455, 2010 WL 1257299, at *3–5 (S.D.N.Y. March 26, 2010).

The Boles II trial involved only Plaintiff's claims against Merck for negligent and strict products liability defective design claims. Punitive damages were not available.

The Boles II trial began on June 7, 2010 and lasted roughly three weeks. At the end of the trial, the jury returned its $8 million verdict in favor of Boles. Shortly thereafter, Merck renewed its motion for judgment as a matter of law and moved in the alternative for a new trial. Merck's renewed motion for judgment as a matter of law raised two issues relevant to the instant motion to certify the Court's October 4, 2010 Opinion and Order for interlocutory appellate review: (1) whether the evidence introduced at trial was sufficient to support a finding that the risks of Fosamax outweighed its benefits; and (2) whether there was evidence sufficient to establish that

Fosamax presented a foreseeable risk of ONJ prior to October 2003.

Merck argued that if the evidence of risks and benefits of Fosamax were balanced "objectively" (i.e., not from the "viewpoint of any specific user"), the trial evidence was insufficient for a reasonable jury to conclude that Fosamax was a defective product. Additionally, Merck argued that Boles did not introduce expert testimony that would support a finding that adverse event reports collected prior to October 2003 put Merck on notice that Fosamax could cause ONJ. Boles argued that Fosamax was defective because it provided no benefit for users who were not osteoporotic at the time they took Fosamax, and that no expert testimony was required to support the jury's finding that the alleged injury was foreseeable.

On October 4, 2010, the Court denied Merck's motions and ordered the remittitur, reducing the verdict to $1.5 million. Noting that a district court could grant a renewed motion for judgment as a matter of law only "where it finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the non-movant," October 4, 2010 Opinion and Order, 742 F. Supp. 2d at 470 (quotations omitted), the Court held that Merck's arguments were contrary to Florida products liability law because no Florida appellate court had applied the standard proposed by Merck and because there was sufficient

evidence from which a reasonable jury could conclude that Merck could have foreseen a connection between the suppression of bone turnover by Fosamax and the occurrence of ONJ, id. at 471–72, 473–75.

II. Discussion

Defendant now moves the Court to certify its October 4, 2010 Opinion and Order for interlocutory appeal pursuant to 28 U.S.C. § 1292(b) with respect to two questions:

(1) May a plaintiff establish that a prescription drug is defective by showing that its risks outweigh its benefits for a subset of the patient population for whom the drug is indicated, regardless of the risk-benefit calculus for the indicated patient population as a whole?
(2) Whether the Court applied an overly broad concept of foreseeability when it ruled that Plaintiff could establish foreseeability without introducing evidence that Fosamax was actually reported to cause ONJ or predicted to cause ONJ by the scientific community prior to Plaintiff's injury?

(See Def.'s Reply Mem. Supp. Mot. to Certify 3-4, ECF No. 314). Under 28 U.S.C. § 1292(b), a district court may certify an order for interlocutory appeal where the order "involves a controlling question of law as to which there is substantial ground for difference of opinion." The statute requires the district court to make a finding "that an immediate appeal from the order may materially advance the ultimate termination of the litigation," and to state this finding in writing. 28 U.S.C. § 1292(b). A district court's certification pursuant to 28 U.S.C. § 1292(b)

"confers no right to appeal but only the right to petition the court of appeals to exercise its discretion to entertain an appeal." Casey v. Long Island R.R. Co., 406 F.3d 142, 146 (2d Cir. 2005).

The first statutory requirement for certification of an interlocutory order for appellate review under 28 U.S.C. § 1292(b) is that the order must involve a controlling question of law. A pure question of law is deemed "controlling" where "reversal of the district court's order would terminate the action." Klinghoffer v. S.N.C. Achille Lauro Ed Altri–Gestione Motonave Achille Lauro In Amministrazione Straordinaria, 921 F.2d 21, 24 (2d Cir. 1990). An issue of law may also be considered controlling if its resolution will "contribute to the termination, at any early stage, of a wide spectrum of cases." von Bulow v. von Bulow, 634 F. Supp. 1284, 1312 (S.D.N.Y. 1986) (citations omitted); see also In re Air Crash Disaster at John F. Kennedy Int'l Airport on June 24, 1975, 479 F. Supp. 1118, 1125 (E.D.N.Y. 1978) (holding that the "multidistrict nature" of an action contributed to the significance of an issue as a controlling question of law). The Second Circuit has recognized that Congress enacted 28 U.S.C. § 1292(b) in part to "assure the prompt resolution of knotty legal problems." Weber v. United States Tr., 484 F.3d 154, 159 (2d Cir. 2007) (emphasis added). Therefore, a "legal question must be stated at a high enough

level of abstraction to lift the question out of the details of the evidence or facts of a particular case and give it general relevance to other cases in the same area of law." McFarlin v. Conseco Services, LLC, 381 F.3d 1251, 1259 (11th Cir. 2004).

The second statutory requirement is that there must be substantial ground for difference of opinion on the issue of law identified as "controlling." There is substantial ground for difference of opinion when the authority on a point of law is in conflict, or when there is a "relative lack of authority on the precise question." In re Prudential Lines, Inc., Nos. 93 Civ. 1481 (CSH), 93 Civ. 7164 (CSH), 1995 WL 79575, at *1 (S.D.N.Y. Feb. 22, 1995). Only orders presenting "contestable" issues may be certified pursuant to 28 U.S.C. § 1292(b). See Ahrenholz v. Bd. of Trs. of Univ. of La., 219 F.3d 674, 675 (11th Cir. 2000).

The final statutory requirement is that appellate review of the order certified for review pursuant to 28 U.S.C. § 1292(b) must materially advance the litigation. Appellate review materially advances litigation "if that 'appeal promises to advance the time for trial or shorten the time required for trial.'" In re Oxford Health Plans, Inc., 182 F.R.D. 51, 53 (S.D.N.Y. 1998) (quoting 16 Charles A. Wright & Arthur Miller, Federal Practice & Procedure § 3930 (2d ed. 1996)). In other words, the ruling of the court of appeals "must substantially

reduce the amount of litigation left in the case." McFarlin, 381 F.3d at 1259.

The Court recognizes that even when the statutory criteria are satisfied, "only exceptional circumstances will justify a departure from the basic policy of postponing appellate review until after the entry of a final judgment." Goldberg v. UBS AG, 690 F. Supp. 2d 92, 102 (E.D.N.Y. 2010) (quotations omitted). "[I]nterlocutory appeal may 'prolong judicial proceedings, add delay and expense to litigants, burden appellate courts, and present issues for decisions on uncertain and incomplete records, tending to weaken the precedential value of judicial opinions.'" Id. at 101 (quoting In re World Trade Cent. Disaster Site Litig., 469 F. Supp. 2d 134, 144 (S.D.N.Y. 2007.)). The Second Circuit has directed "the district courts to exercise great care in making a § 1292(b) certification." Westwood Pharmas., Inc. v. Nat'l Fuel Gas Distribution Corp., 964 F.2d 85, 89 (2d Cir. 1992).

A. Risk-Benefit Analysis Question

On appeal, Merck would challenge the Court's holding that a jury could find in favor of Boles if the jury determined "that Fosamax's risks outweigh its benefits, or lack thereof, when used as indicated for the prevention of osteoporosis." October 4, 2010 Opinion and Order, 742 F. Supp. 2d at 471. According to Merck, Florida law requires the determination of whether a

product is defective by an objective standard, taking into account the benefits and risks of the product to the population at large rather than the benefits and risks of the product to a particular class of users. (See Def.'s Mot. to Certify 2–3, ECF No. 309). Merck takes the position that this is a legal question that has not yet been resolved by the Florida Supreme Court. (Def.'s Mot. to Certify 3). Boles opposes Merck's motion for certification of the Court's October 4, 2010 Opinion and Order and argues that the risk-benefit balancing question is not a controlling question of law and that there is no substantial ground for difference of opinion regarding the proper standard of defective design under Florida law. (Pl.'s Opp. to Def.'s Mot. to Certify 3–4, 7–8, ECF No. 312).

1. Controlling Question of Law

In order to recover in a design-defect action under Florida law, whether pursued on a theory of negligence or a theory of strict products liability, a plaintiff must show that the product in question is "defective or unreasonably dangerous." Marzullo v. Crosman Corp., 289 F. Supp. 2d 1337, 1342 (M.D. Fla. 2003) (citing Siemens Energy & Automation v. Medina, 719 So. 2d 312, 315 (Fla. Dist. Ct. App. 1998)). In the Fosamax MDL, Merck argues that in order for a product to be deemed defective for purposes of a design-defect claim under Florida law, a plaintiff must produce evidence tending to show that the risks of a

product outweigh its benefits from an objective standard--from the perspective of the population at large and not merely from the perspective of a particular user or group of users. In opposing Merck's renewed motion for judgment as a matter of law, Boles argued that the issue of whether a product is defective is a purely factual issue for determination by the jury, and that Florida products liability law is based on Section 402A of the Restatement (Second) of Torts, which in Boles' view does not support Merck's "objective" standard for a defective design claim. (Pl.'s Mem. Opp. to Def.'s Renewed Mot. J.M.O.L. 3, ECF No. 284).

In support of its proposed objective standard, Merck cites the Eleventh Circuit's decision in Jennings v. BIC Corp., 181 F.3d 1250 (11th Cir. 1999), as well as the Restatement (Third) of Torts: Products Liability. In the Jennings case, a three-year-old child playing with a cigarette lighter accidentally lit the plaintiff's pajamas on fire. Plaintiff sued BIC Corporation, the manufacturer of the lighter, in Florida state court for negligence and strict liability due to BIC's failure to child-proof its lighters. Jennings, 181 F.3d at 1253. BIC removed the action to the U.S. District Court for the Middle District of Florida, and the district court held that Florida law did not impose a duty on manufacturers to child-proof its lighters and granted summary judgment in favor of BIC. On

appeal, the U.S. Court of Appeals for the Eleventh Circuit affirmed the district court's ruling. The Eleventh Circuit held that under Florida law, whether a product is "unreasonably dangerous" is determined by an objective standard, id. at 1255 ("[T]he defectiveness of a design is determined based on an objective standard, not from the viewpoint of any specific users."), and therefore the cigarette lighter was not "defective and unreasonably dangerous" merely because use by a young child could be dangerous, id. at 1255–1257.

In reaching its holding that Florida law applies an objective standard to determine whether a product is defective, the Eleventh Circuit relied on the decision of the Florida Third District Court of Appeal in Hobart Corporation v. Siegle ex rel. Hoerber, 600 So. 2d 503 (Fla. Dist. Ct. App. 1992). In Hobart Corporation, the Third District held that the defendants' challenge to the trial court's jury instructions were not properly preserved for appeal, but suggested that the risk-benefit test for defective design requires "application of the objective standard to determine the defective nature of the product" and "consideration of the 'normal public expectation of danger.'" Id. at 504 n.3 (quoting Auburn Mach. Works Co., Inc. v. Jones, 366 So. 2d 1167, 1170 (Fla. 1979)). Furthermore, the Fourth District Court of Appeal has adopted the "objective

standard" language of Jennings and Hobart. See Ligget Group, Inc. v. Davis, 973 So. 2d 467, 475 (Fla. Dist. Ct. App. 2007).

Defendant also partially relies on section 6 of the Restatement (Third) of Torts: Products Liability in support of its argument that Florida law requires the application of an objective standard for defective design. Restatement (Third) § 6 applies only to prescription drugs and medical devices, and presents a narrower scope of tort liability for prescription drug manufacturers than the objective standard urged by Merck. While Merck argues that a defective design claim must be supported by evidence that the overall benefits to the public at large are outweighed by the risks to the public at large, the Restatement (Third) § 6 approach would permit a drug manufacturer to avoid liability on a defective-design claim even if the overall risks of a drug outweigh the benefits of that drug, so long as there is some class of patients for whom the benefits outweigh the risks. See Restatement (Third) of Torts: Products Liability § 6 (1998) (Product is defective where "reasonable health-care providers, knowing of . . . foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.") Both the Restatement (Third) § 6 approach and the objective standard proposed by Defendant require a jury to consider benefits to

persons other than the Plaintiff in determining whether a prescription drug has been defectively designed.

Plaintiff argues that there is no substantial ground for difference of opinion with respect to the question of the proper application of the risk-benefit analysis under Florida law because Florida courts have consistently adhered to the Restatement (Second) of Torts. While the Court persists in its holding that Defendant's proposed objective standard is not an accurate statement of Florida products liability law, no authority cited by Plaintiff expressly rejects the objective standard. See West v. Caterpillar Tractor Co., 336 So. 2d 80 (Fla. 1976) (written prior to the release of the Restatement (Third) of Torts); Alvarez v. Cooper Tire & Rubber Co., --- So.3d ----, 2010 WL 4861514, at *2, *3 n.5 (Fla. Dist. Ct. App. Dec. 1, 2010) (subject to revision or withdrawal pending publication in official reporter). This Court remains hesitant to "stitch into decades of Florida tort law" a new standard for defining design defect, October 4, 2010 Opinion and Order, 742 F. Supp. 2d at 472, but there appears to be substantial ground for difference of opinion on this issue despite the Court's disagreement with Merck's position because, as discussed above, both federal and state courts in Florida have at times applied an objective standard similar to that proposed by Defendant.

The proper legal standard for the risk-benefit test under Florida law is a controlling question of law. It is a purely legal question that may be resolved by an appeal at this point in time without further development of the record, and would have an impact on a number of cases in the Fosamax MDL. Defendant's proposed issue is also "contestable" because Defendant cites authority in support of its position, and the Florida Supreme Court has not ruled on this precise point of law. Therefore, the requirement in 28 U.S.C. § 1292(b) that there be substantial ground for difference of opinion is satisfied.

B. Foreseeability Analysis Question

In seeking appellate review of the Court's October 4, 2010 Opinion and Order, Defendant also contests the standard applied by the Court for determining whether Boles introduced evidence from which a reasonable jury could conclude that the alleged defect in Fosamax was "foreseeable." Proximate causation, which "is concerned with whether and to what extent the defendant's conduct foreseeably and substantially caused the specific injury that actually occurred," is an essential element of Plaintiff's negligence claim. McCain v. Fla. Power Corp., 593 So. 2d 500, 502 (Fla. 1992). According to Defendant, foreseeability is also relevant to Plaintiff's strict liability claim due to the state-of-the-art defense available under Fla. Stat. Ann. § 768.1257.

Defendant claims that the foreseeability of an injury bears on whether an alternative safer design would have been possible given the scientific and technical knowledge that existed prior to October 2003. See Norton v. Snapper Power Equip., Div. of Fuqua Indus., Inc., 806 F.2d 1545, 1549 (11th Cir. 1987) (concluding that "the Florida courts would follow the view that 'state of the art' evidence is relevant both to the plaintiff's case and to the defense.").

The burden to prove that an injury was a foreseeable consequence of a defendant's negligence falls on the plaintiff, see Gooding v. Univ. Hosp. Bldg., Inc., 445 So. 2d 1015, 1018 (Fla. 1984) (quoting William L. Prosser, Law of Torts § 41 (4th ed. 1971)), but generally the defendant has the burden to prove affirmative defenses like the state-of-the-art defense to a strict liability claim, see Ellingham v. Fla. Dep't of Children and Family Servs., 896 So. 2d 926, 927 (Fla. Dist. Ct. App. 2005). Although the foreseeability of a harm is an issue of fact for the jury, Merck argues that, as a matter of law, the foreseeability of ONJ "cannot be established in the absence of any recorded adverse events or any evidence that the scientific community predicted ONJ as a complication of oral bisphosphonates." (Def.'s Reply Mem. Supp. 3).

Though Merck's foreseeability argument implicates a controlling question of law, in order to support certification

under § 1292(b), a movant must show that there is substantial ground for difference of opinion with respect to a question of law. It is firmly established under Florida law that the foreseeability of a particular injury is a question of fact for the jury that is rarely appropriate for disposition as a matter of law. Olson v. Crowell Plumbing & Heating Co., Inc., 48 So. 3d 139, 143 (Fla. Dist. Ct. App. 2010). A plaintiff need only show that "prudent human foresight would lead one to expect that similar harm is likely to be substantially caused by the specific act or omission in question." Fla. Power Corp., 593 So. 2d at 503. Under Florida's state-of-the-art defense, a finder of fact in a design defect case must "consider the state of the art of scientific and technical knowledge and other circumstances that existed at the time of the manufacture, not at the time of loss or injury." Fla. Stat. Ann. § 768.1257. The standard proposed by Merck, that "'foreseeability' cannot be established in the absence of any recorded adverse events or any evidence that the scientific community predicted ONJ as a complication of oral bisphosphonates," (Def.'s Reply Mem. Supp. 3), is without any support in Florida law.

The only Florida case cited by Merck in support of its argument that a risk must be foreseen, rather than merely foreseeable, as of the date the product is distributed, Adams v. G.D. Searle & Co., Inc., 576 So. 2d 728 (Fla. Dist. Ct. App.

1991), is inapposite. In Adams, the Florida Second District Court of Appeals held that Comment k to § 402A of the Restatement (Second) of Torts provides an affirmative defense to a strict liability claim for manufacturers of drugs that "current knowledge and technology cannot make safe for . . . ordinary use, but for which society has a need great enough to justify using . . . despite its dangers." 576 So. 2d at 731 (emphasis added). In addition to proving that a particular drug cannot be made safe for ordinary use and that the societal need for that drug warrants its use despite the obvious dangers, to assert the affirmative defense provided by Comment k, a prescription-drug manufacturer must establish that the benefits of the drug outweigh its known risks as of the date the product is distributed. Id. at 733. This affirmative defense, which is available to the manufacturers of some particularly dangerous drugs, does not define the scope of foreseeability for purposes of proving proximate causation. Merck fails to cite any authority in support of its argument that a particular harm is "foreseeable" only if it was actually observed or expressly predicted. There is no substantial ground for difference of opinion with respect to this issue of law.

In suggesting that this Court described the foreseeability standard as unclear, Merck misquotes the Court's October 4, 2010 Opinion and Order. The Court did not state that the

"appropriate standard for foreseeability in a design defect case" was unclear. The Court stated that it was unclear whether Fla. Stat. Ann. § 768.1257 imposed a burden on a products liability plaintiff to establish foreseeability of a particular injury as part of a prima facie strict liability case, and held that even if there was such a burden, Plaintiff had introduced sufficient evidence to satisfy that burden. October 4, 2010 Opinion and Order, 742 F. Supp. 2d at 474. The question of whether Fla. Stat. Ann. § 768.1257 places a burden on a plaintiff to prove foreseeability to sustain a products liability claim is not the question of law that Merck seeks to certify here. Instead, Merck seeks certification of the question of whether the Court adopted an overly broad concept of foreseeability. (Def.'s Mot. to Certify 7). Under clearly established Florida law, the factual record in the Boles II trial contained sufficient evidence for a reasonable jury to conclude that Plaintiff's injury was a consequence of Fosamax use foreseeable at the time of manufacture. Therefore, the Court does not certify this issue for interlocutory appeal under 28 U.S.C. § 1292(b).

C. Material Advancement of the Litigation

Review of the Court's October 4 Opinion & Order relative to the risk-benefit issue will materially advance the litigation of the Boles case because appellate review at this point will

prevent the possibility that a third trial of this case might be held, only to be followed by a fourth trial should the Second Circuit reverse the Court's ruling on the scope of the risk-benefit test. Clear guidance from the Second Circuit on the risk-benefit test is likely to ensure that a third Boles trial will be the final Boles trial. Additionally, interlocutory appellate review prior to a retrial solely on damages will clarify the law to be applied in the approximately 100 cases in the Fosamax MDL that will be decided under Florida law, and therefore will materially advance the progress of the Fosamax MDL in addition to the Boles case.

This case has been tried twice already, and is a bellwether case in a multidistrict litigation consisting of over 100 cases to be decided under Florida law. The case presents extraordinary circumstances warranting interlocutory appellate review.

III. Conclusion

For the reasons stated above, the Court certifies that the following is a controlling question of law as to which there is substantial ground for difference of opinion:

> May a plaintiff establish that a prescription drug is defective by showing that its risks outweigh its benefits for a subset of the patient population for whom the drug is indicated, regardless of the risk-benefit calculus for the indicated patient population as a whole?

Furthermore, the Court finds that an immediate appeal from the Court's October 4, 2010 Order will materially advance the ultimate termination of this case, as well as the Fosamax MDL. Therefore, the Court **CERTIFIES** the above question for review by the U.S. Court of Appeals for the Second Circuit pursuant to 28 U.S.C. § 1292(b).

Proceedings in the case of Boles v. Merck & Co. Inc., No. 06 Civ. 9455 (JFK), are **STAYED** pending resolution of the appeal or denial of interlocutory appellate review by the Second Circuit. However, no other proceedings in the Fosamax MDL are stayed by this Opinion and Order.

SO ORDERED.

Dated: New York, New York
June 29, 2011

JOHN F. KEENAN
United States District Judge